FORM 1449°	Docket Number	Application Number			
IPE	30000.2USU1	10/789,548			
MERCHANTION DISCLOSURE STATEMENT	Applicants Donald W. Landry and Juan A. Oliver				
IN AN APPLICATION					
	Filing Date	Group Art Unit			
(Use several sheets if necessary)	February 26, 2004	3762			

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
0	5,906,974 (Exhibit 74)	05/25/99	Blue et al.			08/21/96

	FOREIGN PA	TENT DOCUMEN	TS			
 DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANS	LATION
			į		YES	NO
	· ·					

	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
9	Jarcuska, P. et al., "Hemodialysis in Hepatorenal Syndrome Type 1 in Alcoholic Liver Cirrhosis Treated by Continual Terlipressin Infusion in Combination with Albumin Plasmaexpansion," Journal of Hepatology, 2003, 38:194-5, Abstract #675 (Exhibit 75)
6	Lindberg, Jill S. et al., "Lysine Vasopressin (LV) in the Treatment of Refractory Hemodialysis Induced Hypotension (HIH)," Kidney International, 1988, 33:229 (Exhibit 76)

EXAMINER	DATE CONSIDERED
	4-16-05
	· · · · · · · · · · · · · · · · · · ·

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

^{*}Substitute Disclosure Statement Form (PTO-1449)

FORM 1449*			Dock	et Number	A	Application Nu	mber
		0	1PE 3000	0.2USU1	1	0/789,548	
	INFORMATION DISCLOSURE	STATEMENT	Appli				
	IN AN APPLICATION		2 1 2004 Dona	ld W. Landry a	nd Juan A.	Oliver	
		Cessary E	Filing	Date	G	roup Art Unit	
	(Use several sheets if ne	cessary)	Febru	ary 26, 2004	N	lot yet known	
		U.S. PA	TENT DOCUMENTS				
XAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLAS	S FILING	DATE OPRIAT
					<u> </u>		
		FOREIGN P	ATENT DOCUMENT	rs			
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLAS	S TRANS	LATION NO
· :							
	OTHER DOCUM	ENTS (Including	Author, Title, Date	Partinent Par	ies Etc.)		
\sim			opressin Deficiency	· ·		lation of Senti	c Shoel
<u> </u>	Circulation, 199	37, 95:1122-5 (Exhibit 71)				
			ic Regulation of Blo , 1976, 57:1190-2			nal Failure," 7	The .
D			tein antigens and pe proach, 1993, G. G				721
		· Milation Ap	<i>proderr,</i> 1000, G. G.	anagnor ot al.	(eds.), pp 0	5-73 (EXIIIDIL	731
: .							
		- · · · · · · · · · · · · · · · · · · ·					
			•			•	_
			~~···				
							·
			-	•		·	
						F	
							
					·		
		•	· · · · · · · · · · · · · · · · · · ·				
XAMINER	Reson		DATE CONSI	DERED 1505			
XAMINER: I	nitial if reference considered, v	vhether or not c	itation is in conform	ance with MP	EP 609; dra	w line through	h citatio
not in confo	ormance and not considered. I	nclude copy of	this form for next con Patent and Trade	ommunication	to the Appl	icant.	014455

AUS 13 2004 PRETTY & TRADE

FORM 1449*

٨

INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION

(Use several sheets if necessary)

	•
Docket Number	Application Number
30000.2USU1	10/789,548
Applicants	,
Donald W. Landry and J	luan A. Oliver
Filing Date	Group Art Unit
February 26, 2004	Not yet known

		U.S. PAT	ENT DOCUMENTS			
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

		FOREIGN PA	TENT DOCUMEN	TS			
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANS	LATION
						YES	NO
1	W084/03564 (Exhibit 1)	.09/13/84	PCT				×

	OTHER ROCHMENTS (Including Audion Title Date Protection Co.						
	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)						
	Aisenbrey, Gary A. et al., "Vascular Effects of Arginine Vasopressin during Fluid Deprivation in the						
9	Rat," The Journal of Clinical Investigation, 1981, 67:961-8 (Exhibit 2)						
	Ardaillou, Raymond et al., "Secretion and Catabolism of Antidiuretic Hormone in Renal Failure,"						
	Contributions to Nephrology, 1986, 50:46-53 (Exhibit 3)						
	Argent, Nicholas B. et al., "Metabolic clearance rate of arginine vasopressin in severe chronic renal						
	failure," Clinical Science, 1992, 83:583-7 (Exhibit 4)						
	Baldamus, C. A. et al., "Sympathetic and Hemodynamic Response to Volume Removal during						
	Different Forms of Renal Replacement Therapy," Nephron, 1982, 31:324-32 (Exhibit 5)						
$ (a_i) $	Benmansour, Mustapha et al., "Metabolic clearance rate of immunoreactive vasopressin in man,"						
	European Journal of Clinical Investigation, 1982, 12:475-80 (Exhibit 6)						
	Blumberg, Alfred et al., "Extracellular Volume in Patients with Chronic Renal Disease Treated for						
	Hypertension by Sodium Restriction," The Lancet, 1967, 2:69-73 (Exhibit 7)						
	Caillens, Henri et al., "Relationship between Change in Volemia at Constant Osmolality and Plasma						
	Antidiuretic Hormone," Mineral and Electrolyte Metabolism, 1980, 4:161-71 (Exhibit 8)						
1 1 1	Campese, Vito M. et al., "Mechanisms of autonomic nervous system dysfunction in uremia," Kidney						
	International, 1981, 20:246-53 (Exhibit 9)						
	Charra, Bernard et al., "Control of Hypertension and Prolonged Survival on Maintenance						
	Hemodialysis," Nephron, 1983, 33:96-9 (Exhibit 10)						
	Converse, Jr., Richard L. et al., "Paradoxical Withdrawal of Reflex Vasoconstriction as a Cause of						
1 1 1	Hemodialysis-induced Hypotension," The Journal of Clinical Investigation, 1992, 90:1657-65						
	(Exhibit 11)						
	D'Amore, T. Fasanella et al., "Response of plasma vasopressin to changes in extracellular volume						
1 / 1	and/or plasma osmolality in patients on maintenance hemodialysis," Clinical Nephrology, 1985, 23:299-302 (Exhibit 12)						
	Daul, Anton E. et al., "Arterial hypotension in chronic hemodialyzed patients," Kidney International, 1987, 32:728-35 (Exhibit 13)						
(1)	Dunn, Fredrick L. et al., "The Role of Blood Osmolality and Volume in Regulating Vasopressin						
	Secretion in the Rat," The Journal of Clinical Investigation, 1973, 52:3212-9 (Exhibit 14)						

EXAMINER	DATE CONSIDERED
	1 9-11-03
EXAMINER: Initial if reference considered, whether or not citati	on is in conformance with MPEP 609: draw line through citation

if not in conformance and not considered. Include copy of this form for next communication to the Applicant. *Substitute Disclosure Statement Form (PTO-1449)

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

		Siteet 2 of 5
FORM 1449 AUG 13 AUG	Docket Number 30000.2USU1	Application Number 10/789,548
INFORMATION DISCLOSURE STATEMENT	Applicants	·
IN AN APPLICATION	Donald W. Landry and Ju	uan A. Oliver .
	Filing Date	Group Art Unit
(Use several sheets if necessary)	February 26, 2004	Not yet known

	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
Q	Endou, Kyoko et al., "Hemodynamic Changes during Hemodialysis," Cardiology, 1978, 63:175-87 (Exhibit 15)
	Ewing, D. J. and R. Winney, "Autonomic Function in Patients with Chronic Renal Failure on Intermittent Haemodialysis," Nephron, 1975, 15:424-9 (Exhibit 16)
	Fisch, Bruce J. and David M. Spiegel, "Assessment of excess fluid distribution in chronic hemodialysis patients using bioimpedance spectroscopy," <i>Kidney International</i> , 1996, 49:1105-9 (Exhibit 17)
	Foley, Robert N. et al., "Impact of hypertension on cardiomyopathy, morbidity and mortality in end- stage renal disease," <i>Kidney International</i> , 1996, 49:1379-85 (Exhibit 18)
	Friess, U. et al., "Failure of arginine-vasopressin and other pressor hormones to increase in severe recurrent dialysis hypotension," <i>Nephrology Dialysis Transplantation</i> , 1995, 10:1421-7 (Exhibit 19)
	Graybiel, Ashton and R. Earle Glendy, "Circulatory Effects Following the Intravenous Administration of Pitressin in Normal Persons and in Patients with Hypertension and Angina Pectoris," The American Heart Journal, 1941, 21:481-9 (Exhibit 20)
	Grollman, Arthur and E. M. K. Geiling, "The Cardiovascular and Metabolic Reactions of Man to the Intramuscular Injection of Posterior Pituitary Liquid (Pituitrin), Pitressin and Pitocin," The Journal of Pharmacology & Experimental Therapeutics, 1932, 46:447-60 (Exhibit 21)
	Hegbrant, Jörgen et al., "Changes in Plasma Levels of Vasoactive Peptides during Standard Bicarbonate Hemodialysis," Nephron, 1993, 63:303-8 (Exhibit 22)
	Hegbrant, Jörgen et al., "Changes in Plasma Levels of Vasoactive Peptides during Sequential Bicarbonate Hemodialysis," Nephron, 1993, 63:309-13 (Exhibit 23)
	Heintz, B. et al., "Response of vasoactive substances to reduction of blood volume during hemodialysis in hypotensive patients," <i>Clinical Nephrology</i> , 1993, 39:198-204 (Exhibit 24)
	Heintz, B. et al., "Response of Vasoactive Substances to Intermittent Ultrafiltration in Normotensive Hemodialysis Patients," <i>Nephron</i> , 1993, 65:266-72 (Exhibit 25)
	Henderson, Lee W., "Symptomatic hypotension during hemodialysis," <i>Kidney International</i> , 1980, 17:571-6 (Exhibit 26)
	Henrich, William L. et al., "Role of osmolality in blood pressure stability after dialysis and ultrafiltration," <i>Kidney International</i> , 1980, 18:480-8 (Exhibit 27)
	Henrich, William L., "Hemodynamic instability during hemodiaylsis," Kidney International, 1986, 30:605-12 (Exhibit 28)
	Horký, K. et al., "Plasma Concentration of Antidiuretic Hormone in Patients with Chronic Renal Insufficiency on Maintenance Dialysis," <i>Hormone and Metabolic Research</i> , 1979, 11:241-6 (Exhibit 29)
	litake, Kazuhiro et al., "Effect of haemodialysis on plasma ADH levels, plasma renin activity and plasma aldosterone levels in patients with end-stage renal disease," Acta Endocrinologica, 1985, 110:207-13 (Exhibit 30)
	Jaeger, Jack Q. and Ravindra L. Mehta, "Assessment of Dry Weight in Hemodialysis: An Overview," Journal of American Society of Nephrology, 1999, 10:392-403 (Exhibit 31)
9	Jawadi, M. Husain et al., "Regulation of Plasma Arginine Vasopressin in Patients with Chronic Renal Failure Maintained on Hemodialysis," <i>American Journal of Nephrology</i> , 1986, 6:175-81 (Exhibit 32)

EXAMINER	DATE CONSIDERED	
	WATE CONSIDERED	
EVAMINED: Initial if reference and death of the state of	7-/ 4-0)	
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant		

^{*}Substitute Disclosure Statement Form (PTO-1449)

(" " " " " " " " " " " " " " " " " " "	Sheet <u>3</u> of <u>5</u>	
FORM 1449* INFORMATION DISCLESSIFIE STATEMENT	Docket Number 30000.2USU1	Application Number
INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION	Applicants Donald W. Landry and J	uan A. Oliver
,	Filing Date	Group Art Unit
(Use several sheets if necessary)	February 26, 2004	Not yet known

	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
4	Kaliszan, R. et al., "Constrictory Activity of Three New Arginine-Vasopressin (AVP) Analogues (ALA-AVP, SER-ALA-AVP, THR-SER-ALA-AVP) Towards Isolated Rat Tail Artery as Related to AVP Alone," Pharmacological Research Commununications, 1988, 20:377-81 (Exhibit 33)
	Katzarski, Krassimir S. et al., "A Critical Evaluation of Ultrasound Measurement of Inferior Vena Cava Diameter in Assessing Dry Weight in Normotensive and Hypertensive Hemodialysis Patients," American Journal of Kidney Diseases, 1997, 30:459-65 (Exhibit 34)
	Kaufmann, Horacio et al., "Plasma endothelin during upright tilt: relevance for orthostatic hypotension?" The Lancet, 1991, 338:1542-5 (Exhibit 35)
	Kersh, Edward S. et al., "Autonomic Insufficiency in Uremia as a Cause of Hemodialysis-Induced Hypotension," The New England Journal of Medicine, 1974, 290:650-3 (Exhibit 36)
	Landry, Donald W. and Juan A. Oliver, "The Pathogenesis of Vasodilatory Shock," The New England Journal of Medicine, 2001, 345:588-95 (Exhibit 37)
(D	Lazarus, J. Michael et al., "Hemodialysis," The Kidney, 1996, 5th ed., W.B. Saunders Co., Chapter 56, pp 2424-2508 (Exhibit 38)
. (Leypoldt, John K. et al., "Relationship between volume status and blood pressure during chronic hemodialysis," Kidney International, 2002, 61:266-75 (Exhibit 39)
	Mailloux, Lionel U. and William E. Haley, "Hypertension in the ESRD Patient: Pathophysiology, Therapy, Outcomes, and Future Directions," <i>American Journal of Kidney Diseases</i> , 1998, 32:705-19 (Exhibit 40)
	Mallamaci, F. et al., "Autonomic function in uremic patients treated by hemodialysis or CAPD and in transplant patients," Clinical Nephrology, 1986, 25:175-80 (Exhibit 41)
	Matsui, Kuniaki et al., "Effects of Nonhypotensive Hemorrhage on Renal Organ and Urinary Clearances of Vasopressin in the Dog," Endocrinology, 1983, 112:2114-9 (Exhibit 42)
	Minaker, Kenneth L. et al., "Blood Pressure, Pulse, and Neurohumoral Responses to Nitroprusside- Induced Hypotension in Normotensive Aging Men," <i>The Journals of Gerontology</i> , 1991, 46:M151-4 (Exhibit 43)
	Nakashima, Yoshiyuki et al., "Localization of Autonomic Nervous System Dysfunction in Dialysis Patients," American Journal of Nephrology, 1987, 7:375-81 (Exhibit 44)
	Nakayama, Masaaki et al., "Stimulated Secretion of Arginine Vasopressin during Hemodialysis in Patients with Hemodialysis Hypotension," Nephron, 1998, 79:488-9 (Exhibit 45)
	Nies, Alan S. et al., "Hemodialysis hypotension is not the result of uremic peripheral autonomic neuropathy," <i>The Journal of Laboratory and Clinical Medicine</i> , 1979, 94:395-402 (Exhibit 46)
	Padfield, P. L., "Changes of Vasopressin in Hypertension: Cause Or Effect?" The Lancet, 1976, 1:1255-7 (Exhibit 47)
	Pierratos, Andreas et al., "Nocturnal Hemodialysis: Three-Year Experience," Journal of the American Society of Nephrology, 1998, 9:859-68 (Exhibit 48)
	Price, M. R. et al., "Epitope analysis of monoclonal antibody NCRC-11 defined antigen isolated from human ovarian and breast carcinomas," <i>British Journal of Cancer</i> , 1986, 54:393-400 (Exhibit 49)
<u> </u>	Rosansky, S. J. et al., "Effect of osmolar changes on plasma arginine vasopressin (PAVP) in dialysis patients," <i>Clinical Nephrology</i> , 1991, 35:158-64 (Exhibit 50)
6	Rouby, Jean J. et al., "Hemodynamic changes induced by regular hemodialysis and sequential ultrafiltration hemodialysis: A comparative study," <i>Kidney International</i> , 17:801-10 (Exhibit 51)

EXAMINER 1	DATE CONSIDERED 46-05		
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.			
	ent and Trademark Office; U.S. DEPARTMENT OF COMMERCE		

FORM 1449*	AUS 1 3 2004	Docket Number	Application Number
INFORMATION	DISCLOSURE STATEMENT	30000.2USU1 Applicants	10/789,548
IN AN APPLICATION		Donald W. Landry and Juan A. Oliver	
		Filing Date	Group Art Unit
(Use seve	ral sheets if necessary)	February 26, 2004	Not yet known

	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
(p)	Santoro, A. et al., "A Haemodynamic Study of Hypotension During Haemodialysis Using Electrical Bioimpedance Cardiography," <i>Nephrology Dialysis Transplantation</i> , 1990, 5(Suppl 1):147-53 (Exhibit 52)
	Schwartz, Jeffrey and Ian A. Reid, "Effect of Vasopressin Blockade on Blood Pressure Regulation During Hemorrhage in Conscious Dogs," <i>Endocrinology</i> , 1981, 109:1778-80 (Exhibit 53)
	Schwartz, Jeffrey et al., "Role of Vasopressin in Blood Pressure Regulation during Adrenal Insufficiency," Endocrinology, 1983, 112:234-8 (Exhibit 54)
	Shade, R. E. and L. Share, "Metabolic Clearance of Immunoreactive Vasopressin and Immunoreactive [131]iodo Vasopressin in the Hypophysectomized Dog," <i>Endocrinology</i> , 1976, 99:1199-1206 (Exhibit 55)
	Shaldon, S., "Progress from Haemodialysis," Nephron, 1981, 27:2-6 (Exhibit 56)
	Shimamoto, Kazuaki et al., "A Study of Plasma Vasopressin in Patients Undergoing Chronic Hemodialysis," Journal of Clinical Endocrinology & Metabolism, 1977, 45:714-20 (Exhibit 57)
	Shimamoto, Kazuaki et al., "Permeability of Antidiuretic Hormone and Other Hormones Through the Dialysis Membrane in Patients Undergoing Chronic Hemodialysis," Journal of Clinical Endocrinology & Metabolism, 1977, 45:818-20 (Exhibit 58)
	Shiota, Jun et al., "Plasma Atrial Natriuretic Peptide during Hemodialysis with or without Fluid Removal," Nephron, 1990, 55:283-6 (Exhibit 59)
	Sjöquist, P. O. B. et al., "Effect of a Vasopressin Analogue (Nα-glycyl-glycyl-glycyl-[8-lysine]-vasopressin) on Organ Blood Flow in the Pregnant Guinea Pig," Acta Pharmacologica et Toxicologica, 1977, 40:369-77 (Exhibit 60)
	Sjöquist, PO. B. et al., "Actions of a New Vasopressin Analogue (1-deamino-6-carba-[8-arginine]-vasopressin) on Regional Blood Flow in Pregnant Guinea Pigs," Acta Pharmacologica et Toxicologica, 1978, 43:190-5 (Exhibit 61)
	Smith, Clark W. and Martha F. Ferger, "Synthesis and Some Pharmacological Properties of [3-β-(2-Thienyl)-L-alanine]-8-lysine-vasopressin," <i>Journal of Medicinal Chemistry</i> , 1975, 18:822-5 (Exhibit 62)
0	Spiegel, D. M. et al., "Bioimpedance resistance ratios for the evaluation of dry weight in hemodialysis," Clinical Nephrology, 2000, 53:108-14 (Exhibit 63)
9	Stone, William J. and Raymond M. Hakim, "Therapeutic Options in the Management of End-stage Renal Disease," <i>The Principles And Practice of Nephrology</i> , 1995, Chap. 95, pp 650-4 (Exhibit 64)
	Uusimaa, P. et al., "Neurohumoral responses to a single haemodialysis in chronic renal patients," Acta Physiologica Scandinavica, 1999, 165:25-31 (Exhibit 65)
	Vertes, Victor et al., "Hypertension in End-Stage Renal Disease," The New England Journal of Medicine, 1969, 280:978-81 (Exhibit 66)
	Wagner, Jr., Henry N. and Eugene Braunwald, "The Pressor Effect of the Antidiuretic Principle of the Posterior Pituitary in Orthostatic Hypotension," <i>The Journal of Clinical Investigation</i> , 1956, 35:1412-8 (Exhibit 67)
0	Weitzman, Richard E. et al., "Effect of osmolality on arginine vasopressin and renin release after hemorrhage," American Journal of Physiology, 1980, 238:E62-8 (Exhibit 68)

EXAMINER	DATE CONSIDERED	
	4-15-05	
EXAMINER: Initial if reference considered, whether or not citation	on is in conformance with MPEP 609; draw line through citation	
if not in conformance and not considered. Include copy of this form for next communication to the Applicant.		
	ent and Trademark Office; U.S. DEPARTMENT OF COMMERCE	

^{*}Substitute Disclosure Statement Form (PTO-1449)

	AUG 1 3 2004	211661 2 01 2	
FORM 1449*	10	Docket Number	Application Number
	TRADENIARY OF	30000.2USU1	10/789,548
INFORMATION DISCLOSURE STATEMENT		Applicants	
IN AN APPLICATION		Donald W. Landry and Juan A. Oliver	
		Filing Date	Group Art Unit
(Ilsa sava	ral chapte if narageany)	February 26, 2004	Not yet known

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
0		Zerbe, Robert L. et al., "Vasopressin Response to Orthostatic Hypotension," The American Journal of Medicine, 1983, 74:265-71 (Exhibit 69)
0		Ziegler, Michael G. et al., "Norepinephrine clearance, chromogranin A and dopamine β hydroxylase in renal failure," Kidney International, 1990, 37:1357-62 (Exhibit 70)
	-	
		·
		·
	•	
	`	
	1	
		· · · · · · · · · · · · · · · · · · ·

EXAMINER DATE CONSIDERED 4-16-05

EXAMINER: Initial If reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include capy of this form for next communication to the Applicant.

*Substitute Disclosure Statement Form (PTO-1449)

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE